Suggestions for Organizing Information for a CCOP Research Base Application

GENERAL INSTRUCTIONS

In preparing a CCOP Research Base application, you must follow the instructions provided in the **RFA CA-09-022** (*Community Clinical Oncology Program*) and the *Application for a Public Health Service Grant* (**PHS-398**) (11/2007) available at: http://grants.nih.gov/grants/forms.htm and its accompanying packet of forms.

You should refer to RFA-CA-09-022 and the PHS-398 (11/2007) Part, I, II and III for complete instructions.

<u>NOTE</u>: The PHS 398 is organized into three distinct parts, each of which is available as a separate file in MS Word and PDF versions. Applicants will need to use all three parts of the instructions to prepare a complete and acceptable application.

The PHS 398 instructions include:

Part I: Instructions for Preparing the Application

Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan

Part III: Policies, Assurances, Definitions and Other Information

The sample tables provided in this <u>Suggestions for Organizing Information for a CCOP Research Base Application</u> are provided as a supplement to the PHS-398 (11/2007), <u>NOT A REPLACEMENT</u>. These tables are not mandatory, however, they may help the applicant supply all the information required by the RFA while remaining within the page limitations (see **RFA-CA-09-022**, Part II, <u>Section IV.2.B. Content and Form of Application for CCOP Research Base Award</u>). The tables provided in this format may be included in the application as part of the Resources, Progress Report and Human Subject Research sections, as appropriate.

Other information included in this document is intended to provide clarifications to CCOP Research Base applicants regarding specific sections of the PHS 398 application instructions.

Requirement of DUNS Numbers on NIH Applications - Use of the <u>Dun and Bradstreet</u> (D&B) Data Universal Numbering System (DUNS) number is required when applying for Federal grants or cooperative agreements. See <u>NIH Guide Notice dated August 14, 2003</u> and the <u>DUNS Q&A</u> (MS Word) document for more information.

Other Support should NOT be submitted with the application. If this information is included in the application, the application may be returned to the applicant organization WITHOUT peer review. See PHS 398 (11/2007) Part III (Policies, Assurances, Definitions, and Other Information), Section 1.7 - Just-in-Time Policy. Do NOT confuse "Research Support" with "Other Support." Although they sound similar, these parts of the application are very different. See Part III (Policies, Assurances, Definitions, and Other Information).

Appendix: See PHS 398 (11/2007) **Part I** (*Instructions for Preparing and Submitting an Application*), <u>Section 5.7</u> - **Appendix**, for detailed instructions. Include all pertinent information mentioned in RFA-CA-09-022.

Application Due Date: The application due date is indicated in RFA-CA-09-022. The standard receipt dates referenced in the PHS 398 DO NOT apply to applications submitted in response to RFA-CA-09-022.

TABLES SUMMARIZING PROTOCOL ACTIVITY AND CLINICAL SITES

To assist the applicant in providing information sufficient to permit adequate review of study activity and study sites and also maintain clarity and brevity, the following sample tables are provided as suggested formats.

Protocol Activity Tables

Sample Table 1 - Accrual to NCI Approved Cancer Treatment Trials available for use by CCOP

Sample Table 2a - Accrual to NCI Approved Cancer Prevention and Control Trials conducted by your

Research Base for use by CCOP and your members/affiliates, and other Research

Base members/affiliates (if for Inter-group Studies)

Sample Table 2b - Accrual to Inter-group NCI Approved Cancer Prevention and Control Trials

sponsored by other Research Bases for use by your members/ affiliates

Sample Table 3 - Cancer Prevention and Control Concepts Approved by NCI for Protocol Development

Sample Table 4 - Cancer Prevention and Control Concepts under Development

Clinical Site Tables

Sample Table 5 - CCOP Affiliations

Sample Table 6 - Member/affiliate participation in Cancer Prevention and Control

Sample Table 7 - APrevention Members@

Sample Table 8 - Institution audit schedule for Prevention Trials, large-scale and other

<u>NOTE</u>: With respect to the PHS 398 page limitation, each of the Tables 1 through 8 counts as **one page**, even though an applicant may include multiple pages for one or more of these Tables (e.g. 8 pages of Table 1 will count as 1 page against the page limitation referenced in the RFA-CA-09-022).

<u>NOTE</u>: **New applications** are advised to complete all of the attached Sample Tables. Although the tables are not required, they may help the reviewers in their evaluation of the application. Since new applicants have not worked with CCOPS in the past year, they may provide information on treatment accruals from their members and affiliates as an indication of their potential for future CCOP treatment accruals. See **Sample Table 1.** Likewise, new applications may present information regarding cancer prevention and control clinical trials even though these are not NCI approved. See **Sample Tables 2, 3, and 4**.

PHS 398- Part I Instructions for Preparing and Submitting an Application

<u>There is no specific Form Page for the Research Plan</u> – Use Continuation Page.

The **Research Plan** should include sufficient information needed for evaluation of the project. Refer to the instructions as provided in RFA-CA-09-022 under Part II, Section IV.2.B. **Content and Form of Application for CCOP Research Base Award**, sections 1-6 (Note: These sections substitute for Part I- PHS 398, Section 5.5 Items 2-5).

For all other sections under Part I – PHS 398 Research Plan, Section 5.5 Items 1 and 6-17 (where applicable) follow the instructions provided in the PHS 398.